

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
8 December 2005 (08.12.2005)

PCT

(10) International Publication Number
WO 2005/115332 A2

(51) International Patent Classification⁷: **A61K 9/00**

(21) International Application Number:
PCT/US2005/017292

(22) International Filing Date: 17 May 2005 (17.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0410995.5 17 May 2004 (17.05.2004) GB

(71) Applicants (for all designated States except US): **IVAX CORPORATION** [US/US]; 4400 Biscayne Boulevard, Miami, FL 33137 (US). **NORTON HEALTHCARE, LTD.** [GB/GB]; Albert Basin, Royal Docks, London E16 2QJ (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ASHLEY, Adrian** [GB/GB]; Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, Cheshire WA7 3FA (GB). **LAMB, Paul** [GB/GB]; Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, Cheshire WA7 3FA (GB). **MCDONALD, Donald** [US/US]; Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, Cheshire WA7 3FA (GB).

Brook, Runcorn, Cheshire WA7 3FA (US). **MILLER, John** [GB/GB]; Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, Cheshire WA7 3FA (GB). **OLIVER, Martin, J.** [GB/GB]; Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, Cheshire WA7 3FA (GB). **POLLARD, Mathew** [GB/GB]; Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, Cheshire WA7 3FA (GB).

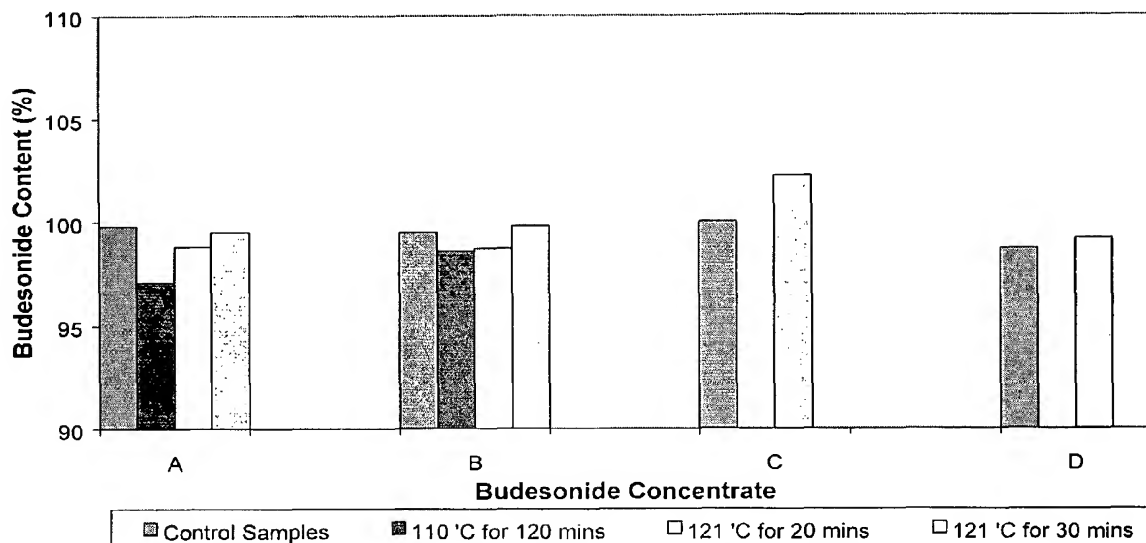
(74) Agent: **STEINBERG, Michael, A.**; Ivax Corporation, 4400 Biscayne Boulevard, Miami, FL 33137 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS



(57) Abstract: The present invention provides a method for the sterilization of a labile glucocorticosteroid, which method comprises heat-treating by moist heat the labile glucocorticosteroid in the form of a suspension for a sterilizing-effective time. The methods and compositions according to the invention are useful as therapeutic tools to prevent, reverse, and/or reduce the symptoms of allergic and/or inflammatory conditions in a mammalian patient. The invention also provides methods and compositions, which may be manipulated and fine-tuned to fit the condition(s) to be treated while producing fewer side effects.



European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *without international search report and to be republished upon receipt of that report*